MAY - 5 2005

K050736

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, Sea Ridge Software, Inc., is providing a summary of safety and effectiveness information regarding the ***imorgan Ultrasound PACS Solutions,*** Picture Archiving and Communications System.

1.1 Company Identification

Sea Ridge Software, Inc.
541 Palmer Lane
Menlo Park CA 94025
Establishment Registration: Application in process
Owner Operator Number: Application in process
Contact: Lloyd Kreuzer, President
Tel/Fax: (650) 328-1037

1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro CA USA 94578-1116
Tel/Fax: (510) 276-2648
Email: regman10@comcast.net

1.3 Date of Submission

March 14, 2005

1.4 Device Name

Classification Name:	Picture Archiving & Communication Sytem
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	**imorgon** Ultrasound PACS Solutions

1.5 Substantial Equivalence

imorgon Ultrasound PACS Solutions software is substantially equivalent to the Siemens (Acuson Corp.) KinetDx Picture Archiving & Communications System (K023772) .

1.6 Device Description and Intended Use

imorgon Ultrasound PACS Solutions is a PACS system, comprised of acquisition components, a central system manager component, a diagnostic workstation component, and an archiving component. The data flow is such that patient and procedure information is optionally delivered to the central system manager, followed by the acquisition of the image objects directly from the image sources or by one of the acquisition components. When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information by selecting the item from the operator work list. The image data is transmitted to and rendered on the user's workstation using the diagnostic workstation components.

imorgon Ultrasound PACS Solutions is also a teleradiology system used to receive DICOM images, scheduling information, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. **imorgon** Ultrasound PACS Solutions is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

1.7 Software Development

Sea Ridge Software, Inc., certifies that the **imorgon** Ultrasound PACS Solutions software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic quality images and associated information to the intended users.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (and optionally supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, by non-programmers, quality control staff, and by potential customers.

Substantial Equivalence:

imorgon Ultrasound PACS Solutions has Indications for Use and a Target Population similar to the Siemens (Acuson Corp.) KinetDx PACS (K023772). All of the functions **imorgon** Ultrasound PACS Solutions performs are available in the listed substantially equivalent device. There are no significant differences between **imorgon** Ultrasound PACS Solutions and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Sea Ridge Software, Inc.
% Mr. Gary J. Allsebrook
Consultant
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K050736
Trade/Device Name: imorgon Ultrasound PACS Solutions
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 14, 2005
Received: March 21, 2005

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050734

Device Name: Sea Ridge Software, Inc., ***imorgon* Ultrasound PACS Solutions),** Picture Archiving and Communications System

Indications For Use:

imorgon Ultrasound PACS Solutions is a medical image and information management system that is intended to transmit, store, retrieve, print and process DICOM digital medical images and associated medical information from various ultrasound imaging systems. It may also be used for general radiogical viewing from other modalities such as MRI, CT or nuclear medicine.

imorgon Ultrasound PACS Solutions is indicated for use by trained medical professionals including, but not limited to, radiologists, physicians and medical technologists. **imorgon** is also indicated for soft copy diagnostic interpretation of medical images and video by physicians trained in such practice.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

David A. Krysiak

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050736